

REMARKS

Claims 1, 2, 5, 8, 17 and 18 were pending as of the Office Action mailed February 19, 2010. The previously pending claims have not been amended and, therefore, no new matter has been added.

Reconsideration and reexamination of the application is respectfully requested in light of the following remarks.

1. Rejection Based on 35. U.S.C. § 103(a)

Claims 1, 2, 5, 8, 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lachman *et al.* in combination with the article, "Encyclopedia of Pharmaceutical Technology," U.S. 5,955,102 (the "'102 patent") and U.S. 5,817,323 (the "'323 patent"). Lachman purportedly teaches a capsule shell comprising gelatin, 40-60% plasticizer, 70-130% water and 0.1% flavor. The article, "Encyclopedia of Pharmaceutical Technology," purportedly teaches that flavors can be included in the shell at small amounts and that the shell contains 5-10% water after drying. The article further purportedly teaches that increasing the water content results in making the shell more soft and stick together and may leak, affecting potency of the shell. The '102 patent purportedly teaches fish oil preferably provided in a gelatin capsule. The '323 patent purportedly teaches a soft gelatin capsule shell comprising a flavoring agent selected from essential oils and fruit flavors, including lemon flavor, or combinations thereof.

Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide gelatin capsules to deliver fish oils comprising a shell containing 5-10% water and 1% of flavoring agent to impart the desired taste as disclosed by the combined teachings of Lachman, the article, "Encyclopedia of Pharmaceutical Technology," and the '102 patent. Further, Examiner asserts that one of ordinary skill in the art would add fruit flavor or replace the essential oil with the fruit flavor (e.g., lemon flavor) as disclosed by the '323 patent.

Applicant respectfully disagrees that the amended claims are *prima facie* obvious over the cited references. Further, Applicant respectfully submits that evidence of unexpected results, long felt need and commercial success rebut any conclusion of obviousness over the cited references.

1.1 Legal Standard

The current standard of obviousness takes into account (1) whether there would have been a “reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does;” and (2) whether there would have been a reasonable expectation of success. (See e.g., *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (“The burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so.”) (internal quotations omitted)). When an invention combines two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does. See, *KSR Intern. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1737 (2007). If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. *Id.*, at 1737. However, a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.*, at 1737.

Evidence of unexpected or unobvious results is objective evidence of nonobviousness, and may be used to rebut a *prima facie* case of obviousness. *In re Wagner*, 371 F.2d 877 (C.C.P.A. 1967); M.P.E.P. § 716.02. Rebuttal evidence may also include evidence of “commercial success, long felt but unsolved needs, [and] failure of others.” *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

A declaration demonstrating the unexpected result that the claimed compound possesses superior activity relative to the prior art is sufficient to rebut a *prima facie* case of obviousness. *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); *Ex parte A*, 17 U.S.P.Q.2d 1716, 1718 (Bd. Pat. App. & Inter. 1990).

1.2 Secondary Consideration

Applicant submits that previous evidence of secondary consideration presented in Applicant’s Office Action response filed Oct 13, 2009 (the "October 2009 Office Action response") is commensurate in scope with the claimed subject matter. Further, this previous

evidence along with additional evidence of secondary consideration submitted herewith are sufficient to rebut any possible conclusion of obviousness over the cited references.

1.2.1. Previous Evidence of Secondary Consideration is Almost Exactly Within the Scope of the Amended Claims

Applicant respectfully submits that evidence of secondary considerations previously presented in Applicant's October 2009 Office Action response is almost exactly commensurate in scope with the amended claims. Examiner asserts that the evidence of nonobviousness and commercial success previously presented by Applicant in the October 2009 Office Action response is not commensurate in scope with the claims of the instant application. Examiner asserts that the claims of the instant application cover all flavored gelatin capsules, wherein the flavor is at a concentration of 1.5%. Examiner contends, however, that the evidence of secondary consideration provided in the Declaration of Opheim of September 21, 2006 and January 16, 2009 and the Declaration of Cooperman of March 29, 2007 (collectively, the "declarations") is limited only to lemon flavor at a specific concentration of 1.0% in the shell and 1.0% in the content of the capsule. Thus, Examiner concludes that the evidence of secondary consideration presented in Applicant's October 2009 Office Action response is not commensurate in scope with the claims of the instant application.

Examiner further asserts that there is no comparative data between the claimed concentration of flavors and amounts outside the claimed concentrations. Applicant respectfully disagrees with the Examiners assertions.

Applicant respectfully points out that the instant claims do not cover all flavors of gelatin capsules as Examiner asserts. In fact, claim 1, as amended in the October 2009 Office Action response, recites a flavored gelatin capsule "comprising. . . a water soluble flavoring. . . present in a concentration of about 1.5%, and the water soluble flavoring is a lemon flavor." See October 2009 Office Action at 2.

Applicant also respectfully submits that the evidence of secondary consideration provided by the aforementioned declarations is not limited to a lemon flavored gelatin capsule at a specific concentration of 1.0% in the shell and 1.0% in the content of the capsule as Examiner asserts. As noted in the Declaration of Opheim of January 16, 2009, the evidence of long felt need and commercial success provided by the Declaration of Opheim of September 21, 2006 and the Declaration of Cooperman of March 29, 2007 relate to gelatin capsules that contain water

soluble flavoring (typically a lemon flavor) present in an amount of approximately 1.5%. See Declaration of Opheim of January 16, 2009 at 1, 2, ¶ 2, 3.

Applicant also respectfully submits that the evidence provided in the aforementioned declarations provides comparative data between the claimed concentration of flavors and amounts outside the claimed concentrations. For example, the Declaration of Opheim of September 21, 2006 provides data showing the number of units sold of the claimed flavored gelatin capsules comprising a dose of fish oil compared to unflavored counterpart products.

Thus, since the secondary evidence provided by the aforementioned declarations relate in part to gelatin capsules comprising a water soluble lemon flavoring at a concentration of about 1.5% as recited in the instant claims, Applicant respectfully submits that the evidence of secondary consideration provided by the aforementioned declarations is almost exactly commensurate in scope with the claims it supports.

1.2.2. Evidence of Secondary Consideration Sufficient Rebut Any Conclusion of Obviousness Over the Cited References

Applicant respectfully submits that the previous evidence of secondary consideration presented in the aforementioned declarations along with additional evidence of secondary consideration submitted herewith sufficiently rebut any possible conclusion of obviousness over the cited references. Applicants respectfully submit that this evidence demonstrates unexpected properties and commercial success of the claimed subject matter and that the claimed subject matter satisfies a long felt need.

Applicant contends that the benefits of fish oil as a nutrient have been well known for many years. See Declaration of Cooperman of March 29, 2009. However, many of the individuals who could benefit from the nutrient do not take it because of its unpleasant taste and aftertaste. *Id.*; Declaration of Bellizzi of August 16, 2010 at 2, ¶ 7. Applicant contends that the claimed subject matter help to meet the long felt need for a palatable fish oil supplement. See Declaration of Cooperman of March 29, 2009. Indeed, substantially improved patient compliance was seen when patients were provided with the claimed subject matter compared to other available fish oil supplements. See Declaration of Cooperman of March 29, 2009; Declaration of Opheim of January 16, 2009 at 1-2, ¶ 3. It is believed that this improved patient compliance is due to the flavoring added to the gelatin shell of the supplements. See Declaration of Cooperman of March 29, 2009.

Flavored gelatin capsule fish oil supplements, including the claimed subject matter, were initially met with skepticism. *See* Declaration of Bellizzi of August 16, 2010 at 2-3, ¶ 8. When Nordic Naturals, Inc. first attempted to establish its fruit flavored gelatin capsule fish oil supplements, it encountered surprise and disbelief from consumers, retail buyers, sales representatives and industry professionals alike over the concept of palatable flavored gelatin capsule fish oil supplements. *Id.* The pleasant smell of the flavored gelatin capsules, however, encouraged people to taste the supplements and most found eating the capsules to be a surprisingly pleasant experience. *See Id.* at 2-3, ¶ 5, 6 and 8.

Despite initial skepticism in the industry and with consumers alike, Nordic Naturals flavored gelatin capsule fish oil supplements, including the claimed subject matter, have gained commercial success. From 2003-2006, Nordic Naturals sold approximately twenty five more times the number of units of flavored gelatin capsules fish oil supplements compared to unflavored counterpart. *See* Declaration of Opheim of September 21, 2006.

Nordic Natural further relates that their flavored gelatin capsule fish oil supplements, including the claimed subject matter, have seen yearly increases in gross revenue from sales since the introduction of the products in 2003. *See* Declaration of Opheim of August 16, 2010 at 2, ¶ 6 and Exhibit A. In 2003, gross revenue from sales of Nordic Naturals' flavored gelatin capsule fish oil supplements were approximately three fold greater than gross revenue from sales of Nordic Naturals' unflavored counterpart products. *Id.* at 2, ¶ 7. In 2009, gross revenue from sales of Nordic Naturals' flavored gelatin capsule fish oil supplements were approximately nineteen fold greater than gross revenue from sales of Nordic Naturals' unflavored counterpart products. *Id.*

The commercial success of Nordic Naturals' flavored gelatin capsule fish oil supplements is directly derived from the claimed flavored gelatin capsules and is not the result of a substantial increase or shift in advertising, consumption by purchasers normally tied to Nordic Naturals, or other business events extraneous to the merits of the flavored gelatin capsule fish oil products. *See* Declaration of Opheim of August 16, 2010 at 2, ¶ 9. Approximately one third of Nordic Naturals' advertising expenses for its flavored gelatin capsule fish oil products in 2008 and 2009 was directed to providing potential consumers with samples of the capsules. *Id.* Thus, a significant portion of Nordic Naturals' advertising expenses was tied to providing potential consumers with an opportunity to taste the flavored gelatin capsule fish oil products. These

opportunities have resulted, in significant part, in the increased sales of the flavored capsule fish oil products discussed above. *Id.*

With the commercial success of Nordic Naturals' flavored gelatin capsule fish oil supplements, including the claimed subject matter, at least fourteen other competitors have mimicked the claimed subject matter in an attempt to gain a market share. *See* Declaration of Opheim of August 16, 2010 at 2, ¶ 8.

Thus, for at least these reasons at a minimum, Patent Owner respectfully submits that evidence of long felt but unresolved needs, unexpected results and commercial success provided herein rebut any conclusion of *prima facie* obviousness over the cited references. Accordingly, Patent Owner respectfully requests the withdrawal of the rejection based on 35 U.S.C. § 103(a).

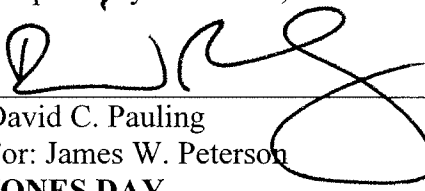
CONCLUSION

Applicant respectfully requests that the foregoing amendments and remarks be entered and made of record in the file history of the above-identified application.

All rejections are believed to be overcome, and reconsideration of the pending claims is respectfully requested. The Examiner is invited to call the undersigned attorney if a telephone call would help resolve any remaining issues.

Respectfully submitted,

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